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10	IN THE UNITED STATES DISTRICT COURT		
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12	FOR THE DISTRICT OF ARIZONA		
13	In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC	
14	Liaomity Litigation	PLAINTIFFS' OPPOSITION TO	
15		DEFENDANTS' MOTION FOR LEAVE TO FILE UNDER SEAL CERTAIN	
16		EXHIBITS IN SUPPORT OF BARD'S REPLY IN SUPPORT OF MOTION TO	
17		EXCLUDE THE OPINIONS OF DAVID	
18		KESSLER, M.D. AND MEMORANDUM OF LAW IN SUPPORT	
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20			
21	I. <u>INTRODUCTION</u>		
22	Plaintiffs oppose C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s (Collectively		
23	referred to as "Bard") Motion to Leave to Seal Certain Exhibits in Support of their Reply to		
24	Exclude Opinions of David Kessler, M.D. and request this Court refrain from sealing the		
25	information at issue as Defendants offer no sufficient justification to seal documents in this		
26	matter.		

Plaintiffs' position here is the same as Plaintiffs set forth in their Opposition to Bard's Request to Seal Plaintiffs' Responses to Defendants' *Daubert* Motions (Dkt. No.

8387 filed 10/24/17), Bard put the documents it seeks to seal at issue. Bard filed *Daubert* motions and replies in every bellwether action against most of Plaintiffs' experts, and Plaintiffs rely on these experts, including Dr. Kessler, to support their Responses to Bard's Motions for Summary Judgments. The documents that Bard urges the Court to seal are not only relevant, but necessary for Plaintiffs to respond to defense motions seeking to defeat Plaintiffs' causes of action and exclude Plaintiffs' experts. Specifically, the schedules to Dr. Kessler's report reflect the Rule 26(a)(2)(B) requirement that mandates an expert identify the facts or data considered in forming his opinions.

The Motions before the Court and the information at issue in Bard's Motion to Seal are of significant importance to the public in general, and particularly to these Plaintiffs, the thousands of other individuals in this litigation who allege harm by Bard's defective products, and all patients implanted with a Bard IVC filter or who may be implanted with a Bard IVC filter. This is a critical health safety litigation with significant stakes and a national scope, and these are the first cases before the MDL court to reach the *Daubert* motion stage. Bard has represented to this Court – and the Plaintiffs, the public, and everyone with an interest in this litigation – that several of Plaintiffs' experts have no factual support for their testimony. This is not true. In fact, Plaintiffs' experts, particularly Dr. Kessler, reviewed and relied on many Bard internal documents which Bard did not provide to its own experts.

Bard's Motion should be denied for the following reasons: (1) Defendants failed to meet the burden to show "compelling reasons" based on specific facts that demonstrate real and actual harm or hardship that will result from disclosure for the documents; and (2) the documents are neither trade secrets nor confidential information; speculative commercial harm is insufficient to seal information and the public is entitled to a right to access these documents.

II. ARGUMENT

A. DEFENDANTS' RELIANCE ON THE PROTECTIVE ORDER ALONE IS INSUFFICIENT TO ESTABLISH THAT THESE DOCUMENTS SHOULD BE FILED UNDER SEAL

On November 9, 2015, the Court granted a stipulated blanket protective order pursuant to Rule 26 of the Federal Rules of Civil Procedure. (Dkt. No. 268). The Order provided a broad definition of what information could meet the "good cause" standard under Rule 26 and allowed Bard to self-designate discovery materials as protected:

The parties, through their respective counsel, stipulate to the entry of a protective order to govern the dissemination of documents, materials, and other information, including the substance and content thereof, designated by any party as confidential and produced by any party in support of motions, in response to written discovery, or during any formal or informal discovery in this litigation subject to the terms as set forth below.

Courts frequently enter umbrella or blanket protective orders to govern voluminous productions to expedite discovery efforts rather than requiring a showing of good cause on a document-by-document basis for all responsive documents produced at the outset of litigation. *United States ex rel. Brown v. Celgene Corp.*, 2016 WL 6542729, at *4 (C.D. Cal. Mar. 14, 2016). Therefore, the protective order in this case did not, in any way, modify Bard's burden to provide particularized showing of good cause with respect to any individual documents or address Bard's burden regarding establishing compelling reasons when seeking to seal dispositive motions, or *Daubert* motions submitted "in connection with" pending motions for summary judgment. *See, San Jose Mercury News, Inc. v. U.S. Dist. Court—Northern Strict (San Jose)*, 187 F.3d 1096 (9th Cir. 1999); *In re Midland Nat. Life Ins. Co. Annuity Sales Practices Litig.*, 686 F.3d 1115, 1120–21 (9th Cir. 2012).

First, Bard seeks an overly broad application of the protective order by requesting protection for an exhibit that Bard created which references cites in Dr. Kessler's Report and Schedules to support their Motion to Exclude Plaintiffs' Expert Dr. Kessler (here on after "Daubert motion"). Both of the cases Bard relies upon for support are factually

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different than the issues before this Court; the motion before the court in *Medics Pharmaceutical* was a Motion for Attorney's Fees and Other Expenses and before the *Phillips* court was a Motion to Compel a Settlement Agreement. *See*, *Medicis Pharm. Corp. v. Acella Pharm.*, *LLC*, No. CV 10-1780-PHX-JAT, 2012 WL 2260928, at *2 (D. Ariz. June 15, 2012). *See also, Phillips ex rel. Estates of Byrd v. Gen. Motors Corp.*, 307 F.3d 1206 (9th Cir. 2002). Next, Bard presumes the Protective Order only affords protection for them and overlooks that the language of the Protective Order also provides relief to Plaintiffs; here, Plaintiffs rely on paragraph 22, "Challenges to Designation of Confidential Information," to support this Opposition and to challenge the sealing of documents based on Bard's failure to show "compelling reasons" balanced with the First Amendment right to access.¹

"Though a stipulated protective order may provide documents designated as confidential are presumptively protected, a party's calling a document confidential pursuant to a protective order does not make it so when it comes to filing the document with the court." *Tillman v. C.R. Bard, Inc.*, 297 F.R.D. 660, 665 (M.D. Fla. 2014)(*quoting Joao Bock Transaction Sys., LLC v. Fidelity Nat. Info. Servs. Inc.*, Case No. 3:13-cv-223-J-32JRK, 2014 WL 279656, at *1 (M.D. Fla. Jan. 24, 2014)). As such, Plaintiffs challenge the designation of the documents at issue, and assert that protective orders are insufficient on their own to establish that documents should be filed under seal.

B. BARD CANNOT MEET THE HEAVY "COMPELLING REASONS" BURDEN REQUIRED TO JUSTIFY SEALING DOCUMENTS SUPPORTING THEIR DAUBERT RESPONSES AND EXHIBITS WHICH FORM THE BASIS OF PLAINTIFFS' RESPONSES TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGEMENT.

¹ There is a default common law right of access to records in civil proceedings. *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597, 55 L. Ed. 2d 570, 98 S. Ct. 1306 (1978). As stated above, the dispositive motion standard was not addressed in the Order. (Dkt. No. 268).

1. The "Compelling Reasons" Standard Applies To *Daubert* Motions Submitted "In Connection With" Pending Motions For Summary Judgment.

The "compelling reasons" standard applies not only to motions for summary judgment, but also to *Daubert* motions submitted "in connection with" pending motions for summary judgment because "exclusion of expert testimony could cause a crippling blow to the sponsoring party's ability to prove its case." *See, Open Text S.A. v. Box, Inc.*, 13-CV-04910-JD, 2014 WL 7368594, at *2 (N.D. Cal. Dec. 26, 2014)(*citing In re Midland Nat. Life Ins. Co. Annuity Sales Practices Litig.*, 686 F.3d 1115, 1120–21 (9th Cir. 2012).

When *Daubert* motions seeking to exclude the testimony of experts are "aimed squarely at the other side's damage methodology" and "in connection with" pending motions for summary judgment, the Ninth Circuit applies the "compelling reasons" standard and requires the moving party to comply with this standard instead of the "good cause" standard. *Id.* A *Daubert* motion does not, on its own, conclusively invoke the higher burden of proof. *Id.* A *Daubert* motion must be connected to a pending summary judgment motion, effectively "dispositive of a motion for summary judgment." *Open Text S.A. v. Box, Inc.*, at *2. (*quoting Lust ex rel. Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 597 (9th Cir.1996).²

Here, Plaintiffs rely on Dr. Kessler to establish genuine issues of material facts "in connection with" Plaintiffs' Omnibus Separate Statement of Facts in Support of Their Responses to Defendants' Motions for Summary Judgments in the Bellwether Cases, (Dkt. 7950). Defendants' *Daubert* Motion to Exclude Dr. Kessler is "aimed squarely at the other side's damage methodology" and Plaintiffs' depend on Dr. Kessler's expert report, schedules, and testimony "in connection with" pending motions for summary judgments.³

² Non-dispositive motions "are often 'unrelated, or only tangentially related, to the underlying cause of action," and, as a result, the public's interest in accessing dispositive materials does "not apply with equal force" to non-dispositive materials. *Kamakana v. City & County of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006).

³ Also addressed in Plaintiffs' Opposition to Bard's Request to Seal Plaintiffs' Responses to Defendants' *Daubert* Motions for Plaintiffs experts Robert McMeeking, PhD. and Derek Muehrcke, M.D. (Dkt. No. 8387).

As such, Bard is required to show "compelling reasons" to seal based on specific facts that actual resulting harm outweighs the strong presumption of access to court records.

2. Standard for Sealing *Daubert* Motions Submitted "In Connection With" Pending Motions For Summary Judgment.

Courts have historically recognized a "general right to inspect and copy public records and documents, including judicial records and documents." Nixon v. Warner Communications, Inc., 435 U.S. 589, 597 (1978). To overcome the "strong presumption in favor of access" in relation to a dispositive motion, the party seeking to seal bears the burden of overcoming this presumption by meeting the "compelling reasons" standard. *Kamakana* v. City & County of Honolulu, 447 F.3d 1172, 1178 (9th Cir. 2006). "That is, the party must articulate compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure, such as the public interest in understanding the judicial process." Id. at 1178-79 (internal citations and quotations omitted). "In turn the Court must conscientiously balance the competing interest of the public and the party who seeks to keep certain judicial records secret." *Id.* at 1179. (internal citations and quotations omitted). Conclusory statements concerning hypothetical harm that may result from public disclosure of such documents fail to carry this burden *Id*. at 1182. Whenever a document has been filed in connection with a dispositive motion, even if the document had been previously sealed upon a showing of good cause, the "compelling" reasons" standard applies. *Id.* at 1179-80. *See also, In re Pradaxa (Diabigatran Etexilate)* Products Liability Litigation, 2014 WL 321656, at *4 (S.D. Ill. Jan. 29, 2014) (ordering a German drug maker to de-designate 85 documents previously marked as confidential and ordering the court clerk to unseal the documents).

The Ninth Circuit disfavors sealing broad categories of documents; particularly where specific details regarding the need for such protection are absent. *Kamakana* at 1184. The moving party must demonstrate a genuine need and provide a detailed explanation of that need and specific facts supporting the harm that may result. *Id.* at 1182-84.

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The "compelling reasons" standard is a strict one, and requires that the party seeking to seal material show specific, individualized reasons for sealing the material, "without relying on hypothesis or conjecture," such as "whether disclosure of the material could result in improper use of the material for scandalous or libelous purposes or infringement upon trade secrets." *See Pintos v. Pacific Creditors Ass'n*, 605 F.3d 665, 679 & n.6 (9th Cir. 2009). "Simply mentioning a general category of privilege, without any further elaboration or any specific linkage with the documents, does not satisfy the burden." *Kamakana*, 447 F.3d at 1179.

Then the district court must weigh the "relevant factors" and base its decision "on a compelling reason," and "articulate the factual basis for its ruling, without relying on hypothesis or conjecture." *Pintos v. Pac. Creditors Ass'n*, 605 F.3d 665, 679 (9th Cir. 2010)(*citing Hagestad v. Tragesser*, 49 F.3d 1430, 1434 (9th Cir.1995)). "Relevant factors" include the "public interest in understanding the judicial process and whether disclosure of the material could result in improper use of the material for scandalous or libelous purposes or infringement upon trade secrets." *Hagestad*, 49 F.3d at 1434 (quoting *EEOC v. Erection Co., Inc.*, 900 F.2d 168, 170 (9th Cir.1990) (*See also, Kamakana* 447 F.3d at 1179, "compelling reasons sufficient to outweigh the public's interest in disclosure and justify sealing court records exist when such court files have become a vehicle for "improper purposes, such as the use of records to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets"). However, the mere fact that unsealing such records may lead to embarrassment, incrimination, or exposure to litigation is not a compelling reason to seal court records. *Id.*

As will be discussed below, Bard has not provided "compelling reasons" to seal any of the documents at issue related to Dr. Kessler nor has Bard shown that these documents contain trade secrets or confidential information.

C. BARD HAS FAILED TO MEET ITS BURDEN TO SHOW COMPELLING REASONS BASED ON SPECIFIC FACTS THAT ACTUAL RESULTING HARM OUTWEIGHS THE STRONG PRESUMPTION OF ACCESS TO COURT RECORDS.

Bard must establish "compelling reasons" to support redacting cites from documents listed in Defendants' Exhibit A related to Dr. Kessler. Bard generally claims that the information in Bard's cited documents contain "dozens of confidential Bard documents, including technical and design files, testing documents, internal adverse event investigations and analysis, design and risk management documents, and numerous internal e-mails between high-level Bard employees." (Dkt. 8232 at 3). Other than such vague generalities, Bard offers no specific grounds or reasons why disclosure of the information from these specific documents would put it at any potential competitive disadvantage or provide Bard's competitors with an economic advantage. Nor can such a showing be made. Notably, Bard's motion is devoid of any supporting affidavits, declarations or other evidence.⁴

Bard does not provide specific, individualized reasons for sealing nor to justify that its redactions are necessary to protect trade secrets; *See, Pintos v. Pacific Creditors Ass'n*, 605 F.3d 665, 679 & n.6 (9th Cir. 2009). It is clear from a tertiary review of Exhibit A to Bard's Motion that it is lacking compliance with the Ninth Circuit's elevated "compelling reasons" standard based on *Daubert* motions submitted "in connection with" pending motions for summary judgment.

Bard's failure to provide specific factual support for its claims of trade secret is strikingly similar to the factual deficiency in *Biocore*, *Inc. v. Khosrowshahi*, 96 F. Supp. 2d 1221, 1231-32 (D. Kan. 2000) ("*Biocore*"). In *Biocore*, a company alleged that its business

⁴ To date, Bard has only submitted one corporate witness declaration to support a Motion to Seal. For Bard's Second Amended Motion to Seal Documents Filed in Support of Its Motion for Summary Judgment Regarding Preemption (Dkt. No 7853), Bard submitted the Declaration of Robert Carr; this declaration provided general statements and lacked both specific details demonstrating a genuine need for sealing and specific facts supporting the harm that may result as required by the Ninth Circuit. *See*, *Kamakana* at 1184.

procedures for conducting clinical trial studies and for obtaining FDA clearance under FDA regulations were trade secrets. As in the present matter, *Biocore*, the plaintiff, failed to produce evidence describing the procedures, and failed to explain how its procedures differed from others in the field or from the general FDA requirements. The court ruled that Biocore had failed to establish the documents were trade secret because "[p]laintiffs failed to meet their burden of proving that their method of conducting efficacy studies is different from methods that are matters of general knowledge in the trade." Id. at 1231. The court explained its decisions as follows:

While both of these items are marked confidential, they contain nothing but basic information. Plaintiffs do not show that the validation protocol and validation procedures are not generally known. They provide no evidence regarding protocols and procedures which other companies use. Neither document describes any procedure that appears to be out of the ordinary; the documents list obvious procedures which every company in the field would also follow with slight but obvious variations for specific equipment and products.

Id. at 1232 (internal citations omitted). As in *Biocore*, Bard has failed to provide anything beyond general and unsupported claims.

Bard seeks to seal documents after the discovery period has closed and just prior to trial. Plaintiffs' position is that Bard has not shown "compelling reasons" to the information contained in the Schedules, precisely Bard has not argued with specificity the substance and portions of the documents they seek to seal. Moreover, no arguments have been presented as to the nature and substance of these documents that justify sealing nor has a description of the specific injury, competitive or otherwise, that Bard is likely to experience if these documents are not sealed.

D. BARD'S DOCUMENTS CANNOT BE CHARACTERIZED AS TRADE SECRETS.

Bard's documents at issue cannot be objectively characterized as trade secrets or confidential information. Bard asserts that the "potential for abuse and for competitive harm is real." The information contained in these documents has no inherent or intrinsic actual

or potential value. The majority of the information is stale, and several of the documents involve products which have not been sold since 2009. Secret or confidential information becomes "stale" over time and thus rule that a previous confidential designation no longer applies. *See*, *Salomon Smith Barney*, *Inc. v. HBO & Co.*, 2001 WL 225040, at *2 (S.D.N.Y. Mar. 7, 2001) (stating that although there may have been reasons to mark documents as confidential at the time they were generated, there was insufficient cause shown "for so treating them today").

Bard argues generally that the medical device industry is competitive. Bard appears to supplant "confidentiality" with "trade secret" because "[b]usiness information alleged to be confidential 'is not entitled to the same level of protection from disclosure as trade secret information." *Republic of Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 663 (3d Cir. 1991) (*quoting Littlejohn v. BIC Corp.*, 851 F.2d 673, 685 (3d Cir. 1988)). Trade secrets have been defined in the Ninth Circuit as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." *In re Elec. Arts, Inc.*, 298 F. App'x 568, 569–70 (9th Cir. 2008) (applying the Restatement's definition of trade secret in the record-sealing context).

The documents Bard seeks to redact do not include formulas, patterns, or compilations of information which would provide an opportunity or advantage to Bard's competitors. There is nothing in these documents that would provide any value to any competitor or to Bard in keeping them a secret from its competitors. Bard has not elucidated a compelling reason to redact this information and speculative commercial harm is insufficient to overcome the "strong presumption in favor of public access."

III. <u>CONCLUSION</u>

Bard fails to establish "compelling reasons" based in fact that outweighs the general history of access and the public policies favoring disclosure; as such, Bard failed to establish specific facts showing that these documents are "trade secrets" and that it would suffer a serious and specific harm from disclosure of this information. Bard's motion does not

1	articulate a "narrowly tailored" remedy as required when contemplating suppression of the	
2	public's First Amendment right of access to these documents.	
3	RESPECTFULLY SUBMITTED this 1st day of November, 2017.	
4	GALLAGHER & KENNEDY, P.A.	
5	By: /s/Mark S. O'Connor	
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14	Laguna Beach, California 92660	
15	Counsel for Plaintiffs	
16	I hereby certify that on this 1 st day of November, 2017, I electronically transmitted	
17	the attached document to the Clerk's Office using the CM/ECF System for filing and	
18	transmittal of a Notice of Electronic Filing.	
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20	/s/ Gay Mennuti	
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